

PATENT

**REMARKS**

In the Office Action, claims 1-26 are rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for operating parameters, does not reasonably provide enablement for "operating parameters, other than pacing pulse width and pacing pulse amplitude, require adjustment."

In the Office Action, claims 1-3, 5-17, 19, and 21-26 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Number 5,417,718 to Kleks et al.

In the Office Action, claims 4, 18, and 20 are rejected under 35 U.S.C. §103(a) as being unpatentable over Kleks et al. in view of U.S. Patent Number 5,127,402 to Mann et al.

In response thereto, claims 3, 4, 18 and 20 have been cancelled, and claims 1, 8, 11-14, 19 and 21 have been amended. Accordingly, claims 1, 2, 5-17, 19 and 21-26 are now pending. Following is a discussion of the patentability of each of the pending claims.

**Preliminary Matter**

In response to the rejection of claims 1-26 under 35 U.S.C. §112, first paragraph, it is respectfully submitted that the specification of the present application does provide enablement for "operating parameters, other than pacing pulse width and pacing pulse amplitude, require adjustment." Please note the following sections of the specification:

Page 3, line 29 through page 4, line 11, states:

"[w]hile conventional capture tracking systems do reducing power usage by automatically setting the systems to reduce power usage by automatically setting the pacing pulse output energy, they fail to address other programmable parameters that affect the operation of implantable pacemakers and ICDs. For example, ..."

## PATENT

Page 4, lines 23-30, states:

"[s]pecifically, many of the programmable features that have been added to modern stimulation devices have simply been added to the existing architecture, without consideration of the automatically adjusting stimulation pulse energies. Accordingly, the shortcomings associated with the related are have heretofore not been adequately addressed. The present invention addresses such problems by providing a system and method that have not previously been proposed."

Page 6, lines 5-7 states:

"[a]dditionally, in one embodiment, the value for the operating parameter is modified by the control unit based on an additional variable, in combination with the pacing pulse output energy."

Accordingly, it is respectfully submitted that the rejection of claims 1-26 under 35 U.S.C. §112, first paragraph, be withdrawn.

Independent Claim 1

Claim 1 recites a method for operating an implantable cardiac stimulation device. The method comprises dynamically modifying a pacing pulse energy, determining whether one or more operating parameters require adjustment in response to a change in the pacing pulse amplitude, and adjusting a value for an operating parameter to a new value if the operating parameter requires adjustment, wherein the new value is based upon the pacing pulse energy. The one or more operating parameters are other than pacing pulse width and pacing pulse amplitude, and the one or more operating parameters comprise at least one of a blanking period, a safety standby, a maximum sensor rate, a refractory period, a lead supervision, a fast recharge, and a block overlap.

The *Kleks et al.* reference discloses an autocapture system which automatically maintains energy of a stimulation pulse at a level just above that which is needed to effectuate capture. Periodically, and/or at programmed intervals or events, a capture verification test is performed. During the capture verification test, a pulse generator determines a polarization template for a particular stimulation energy and for each of a

## PATENT

plurality of sensitivity or threshold settings. A determination is also made as to which sensitivity settings yield capture.

The *Kleks et al.* reference does not disclose or suggest adjusting a value for an operating parameter to a new value if the operating parameter requires adjustment, wherein the new value is based upon the pacing pulse energy and wherein the operating parameter comprises at least one of a blanking period, a safety standby, a maximum sensor rate, a refractory period, a lead supervision, a fast recharge, and a block overlap. It appears that the *Kleks et al.* reference discloses adjusting sensitivity settings (i.e., gain settings of a sense amplifier) to a new value in response to a change in the pacing pulse energy, wherein a table of polarization templates is created as a function of sensitivity settings for a particular stimulation energy. However, nowhere does the *Kleks et al.* reference disclose or suggest adjusting an operating parameter such as a blanking period, safety standby, maximum sensor rate, refractory period, lead supervision, fast recharge, and block overlap.

It is apparently conceded that the *Kleks et al.* reference does not disclose or suggest adjusting a maximum sensor rate in response to a change in the pacing pulse energy. For this reason, it appears the Examiner has introduced the *Mann et al.* reference. It is respectfully submitted that any rejection of claim 1 based on a combination of these references, however, would be improper. "Before the PTO may combine the disclosures of two or more prior art references in order to establish prima facie obviousness, there must be some suggestion for doing so." *In re Jones*, 21 USPQ 2d 1941 (Fed. Cir. 1992). In this connection, the Office Action fails to point to anything in the references that would suggest the apparent proposed reconstruction to pick and chose among the isolated disclosures in the prior art to deprecate the claimed invention." *In re Fritch*, 23 USPQ 2d 1780, 1784 (Fed. Cir. 1992). As there is no suggestion in the references for the proposed combinations, any rejection of claim 1 would fail to present a prima facie case of obviousness.

Furthermore, the *Mann et al.* reference is directed to an implantable stimulation device that limits the utilization of high power consumption modes during low battery periods. When the battery is below a predetermined threshold, the implantable stimulation device is switched from a high current drain mode of operation to progressively lower current drain modes of operation. In one embodiment, the maximum sensor rate is

## PATENT

decreased when the battery voltage is below a threshold voltage level. The present application, on the other hand, addresses the problem that "many of the programmable features that have been added to modern stimulation devices have simply been added to the existing architecture without consideration of the automatic adjustment of stimulation pulse energies." In one embodiment of the present application, the implantable cardiac device determines whether one or more operating parameters require adjustment in response to a change in the pacing pulse energy and adjusts a value for an operating parameter to a new value if the operating parameter requires adjustment, wherein the new value is based upon the pacing pulse energy.

Accordingly, it is respectfully submitted that claim 1 is in condition for allowance.

Dependent Claims 2, 5-7, 22, and 23

Claims 2, 5-7, 22, and 23 depend from claim 1 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 8

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 8 is in condition for allowance.

Dependent Claims 9, 10, and 24

Claims 9, 10, and 24 depend from claim 8 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

Independent Claim 11

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 11 is in condition for allowance.

Dependent Claims 12-17 and 19

Claims 12-17 and 19 depend from claim 11 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

## PATENT

Independent Claim 21

For at least the same reasons discussed above with regards to claim 1, it is respectfully submitted that claim 21 is in condition for allowance.

Dependent Claims 25 and 26

Claims 25 and 26 depend from claim 21 and are similarly patentable. Accordingly, it is respectfully submitted that these claims are in condition for allowance.

CONCLUSION

In light of the above claim amendments and remarks, it is respectfully submitted that the application is in condition for allowance, and an early notice of allowance is requested.

Respectfully submitted,

8/4/04

Date

Pacesetter, Inc.  
15900 Valley View Court  
Sylmar, CA 91392-9221  
818/493-3157  
818/362-4795 (fax)

*Ronald S. Tamura*

Ronald S. Tamura, Reg. No. 43,179  
Patent Attorney for Applicant